I

118TH CONGRESS
1ST SESSION

H. R. 6109

To amend the Internal Revenue Code of 1986 to establish the generic drugs and biosimilars production credit, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 26, 2023

Ms. TENNEY introduced the following bill; which was referred to the Committee on Ways and Means

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A BILL

To amend the Internal Revenue Code of 1986 to establish the generic drugs and biosimilars production credit, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Producing Incentives for Long-term production of Lifesaving Supply of Medicine Act'' or the ''PILLS Act''.

SEC. 2. GENERIC DRUGS AND BIOSIMILARS PRODUCTION CREDIT.

(a) IN GENERAL.—Subpart D of part IV of chapter A of chapter 1 of the Internal Revenue Code of 1986 amended by adding at the end the following new section:

"SEC. 45BB. GENERIC DRUGS AND BIOSIMILARS PRODUCTION CREDIT.

''(a) IN GENERAL.—

''(1) ALLOWANCE OF CREDIT.—For purposes of section 38, the generic drugs and biosimilars production credit for any taxable year is an amount equal to the credit amount determined under subsection (b) with respect to each eligible component which is—

''(A) produced by the taxpayer in the United States, and

''(B) sold by such taxpayer to an unrelated person during the taxable year.

''(2) PRODUCTION AND SALE MUST BE IN TRADE OR BUSINESS; UNRELATED PERSON.—Rules similar to the rules of paragraphs (2) and (3) of section 45X(a) shall apply.

''(3) DISALLOWANCE OF CREDIT.—The credit under this subsection shall not be allowed to any taxpayer which, at any time during the taxable year, was a foreign entity of concern (as defined in section

9901(8) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (15 U.S.C. 4651)).

''(b) CREDIT AMOUNT.—

''(1) IN GENERAL.—Subject to paragraph (4), the amount determined under this subsection with respect to any eligible component shall be an amount equal to—

''(A) the value added to such component by the taxpayer, multiplied by

''(B) the base credit percentage.

''(2) VALUE ADDED.—The value added to a component by a taxpayer is an amount equal to—

''(A) the gross receipts received by the taxpayer from the sale of the eligible component, minus

''(B) the cost of eligible components purchased from an unrelated person in connection with the production of the component by the taxpayer.

''(3) BASE CREDIT PERCENTAGE.—

''(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the base credit percentage shall be 30 percent.

"(B) INCREASED BASE CREDIT PERCENTAGE FOR CERTAIN ELIGIBLE COMPONENTS.—The base credit percentage shall be 35 percent in the case of the final production of—

"(i) a drug substance,

"(ii) a drug product, or

"(iii) a biological product.

"(C) DOMESTIC CONTENT BONUS CREDIT.—

"(i) IN GENERAL.—In the case of an eligible component which contains domestic content, the base credit percentage determined under this paragraph (determined without regard to this subparagraph) shall be increased by an amount equal to—

"(I) the domestic content percentage, multiplied by

"(II) 0.20.

"(ii) DOMESTIC CONTENT PERCENTAGE.—For purposes of this paragraph, the term 'domestic content percentage' means the percentage of the total cost of the bill of materials of the eligible component that is attributable to materials and compo-

nents that were produced in the United States.

"(iii) DOCUMENTATION RULES.—

"(I) RECORDKEEPING.—No domestic content bonus credit shall be determined under this subparagraph unless the taxpayer provides documentation supporting the domestic content percentage (in such form and manner as the Secretary shall prescribe).

"(II) CERTIFICATION BY UNRELATED PARTY.—In the case of materials or components provided to the taxpayer by an unrelated party, the Secretary shall accept certification (in such form and manner as the Secretary shall prescribe) by such unrelated party that the materials or components were produced in the United States.

"(4) PHASEOUT.—

"(A) IN GENERAL.—In the case of any eligible component sold after December 31, 2029, the amount determined under this subsection

with respect to such component shall be equal to the product of—

"(i) the amount determined under paragraph (1) with respect to such component (determined without regard to this paragraph after the application of paragraphs (2) and (3)), multiplied by

"(ii) the phaseout percentage under subparagraph (B).

"(B) PHASEOUT PERCENTAGE.—The phase out percentage under this subparagraph is equal to—

"(i) in the case of an eligible component sold during calendar year 2030, 75 percent,

"(ii) in the case of an eligible component sold during calendar year 2031, 50 percent,

"(iii) in the case of an eligible component sold during calendar year 2032, 25 percent,

"(iv) in the case of an eligible component sold after December 31, 2032, 0 percent.

"(c) DEFINITIONS.—For purposes of this section—

''(1) ELIGIBLE COMPONENT.—

''(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the term 'eligible component' means—

''(i) an approved generic drug,

''(ii) a licensed biosimilar, and

''(iii) any drug substance, intermediate, raw material, starting material, reagent, component, in-process material, inactive ingredient, container closure system, packaging, quality testing, or other material or service used, or sold with intention for use, in the production of an approved generic drug or a licensed biosimilar.

''(B) EXCLUSION OF CERTAIN COMPONENTS.—The term 'eligible component' shall not include a component any portion of the production of which occurred at a facility which is the subject of a warning letter—

''(i) which was issued by the Food and Drug Administration on or after September 1, 2009, and

''(ii) with respect to which the Food and Drug Administration has not issued a close-out letter.

''(C) APPLICATION WITH OTHER CREDITS.—The term 'eligible component' shall not include any property which is produced at a facility if the basis of any property which is part of such facility is taken into account for purposes of the credit allowed under section 48F after the date of the enactment of this section.

''(2) APPROVED GENERIC DRUG.—The term 'approved generic drug' means—

''(A) a drug for which an approval of an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is in effect, or

''(B) an authorized generic drug.

''(3) AUTHORIZED GENERIC DRUG; DRUG SUBSTANCE; DRUG PRODUCT.—The terms 'authorized generic drug', 'drug substance', and 'drug product' have the respective meanings given such terms in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation).

''(4) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in

section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

''(5) LICENSED BIOSIMILAR.—The term 'licensed biosimilar' means a biological product for which a biologics license has been issued under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(6) PRODUCED IN THE UNITED STATES.—The term 'produced in the United States' means that all the production of the material or component takes place in the United States, regardless of the origin of the subcomponents of such material or component.

''(7) PRODUCTION.—The term 'production' means all steps in the manufacture, propagation, and preparation of an eligible component, including synthesis, mixing, granulating, milling, molding, lyophilizing, tableting, encapsulating, coating, sterilizing, testing, filling, labeling, packaging, and storage prior to release by the manufacturer.

''(d) SPECIAL RULES.—Rules similar to the rules of paragraphs (1), (3), and (4) of section 45X(d) shall apply.''.

(b) ELECTIVE PAYMENT.—Section 6417(a) of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

''(13) The generic drugs and biosimilars production credit determined under section 45BB.''.

(c) CONFORMING AMENDMENTS.—

(1) Section 38(b) of the Internal Revenue Code of 1986 is amended—

(A) in paragraph (40), by striking ''plus'' at the end, and

(B) in paragraph (41), by striking the period at the end and inserting '', plus'', and by adding at the end the following new paragraph:

''(42) the generic drugs and biosimilars production credit determined under section 45BB(a).''.

(2) The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 45BB. Generic drugs and biosimilars production credit.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to generic drugs and biologics produced after the date of enactment of this Act.

SEC. 3. GENERIC DRUGS AND BIOSIMILARS INVESTMENT CREDIT.

(a) IN GENERAL.—Subpart E of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 48E the following new section:

"SEC. 48F. GENERIC DRUGS AND BIOSIMILARS INVESTMENT CREDIT.

"(a) ESTABLISHMENT OF CREDIT.—For purposes of section 46, the generic drugs and biosimilars investment credit for any taxable year is an amount equal to 25 percent of the qualified investment for such taxable year with respect to any qualified facility of an eligible taxpayer.

"(b) QUALIFIED INVESTMENT.—

"(1) IN GENERAL.—For purposes of subsection (a), the qualified investment for any taxable year is the basis of any qualified property placed in service by the taxpayer during such taxable year which is part of a qualified facility.

"(2) QUALIFIED PROPERTY.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'qualified property' means property—

"(i) which is tangible property,

"(ii) with respect to which depreciation (or amortization in lieu of depreciation) is allowable,

"(iii) which is—

"(I) constructed, reconstructed, or erected by the taxpayer, or

"(II) acquired by the taxpayer if the original use of such property commences with the taxpayer, and

"(iv) which is integral to the operation of the qualified facility.

"(B) BUILDINGS AND STRUCTURAL COMPONENTS.—

"(i) IN GENERAL.—The term 'qualified property' includes any building or its structural components which otherwise satisfy the requirements under subparagraph (A).

"(ii) EXCEPTION.—Clause (i) shall not apply with respect to a building or portion of a building used for offices, administrative services, or other functions unrelated to the production of eligible components.

''(3) QUALIFIED FACILITY.—For purposes of this section, the term 'qualified facility' means a facility the primary purpose of which is the production of eligible components.

''(4) COORDINATION WITH REHABILITATION CREDIT.—The qualified investment with respect to any qualified facility for any taxable year shall not include that portion of the basis of any property which is attributable to qualified rehabilitation expenditures (as defined in section 47(c)(2)).

''(5) CERTAIN PROGRESS EXPENDITURE RULES MADE APPLICABLE.—Rules similar to the rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of subsection (a).

''(c) DEFINITIONS.—For purposes of this section—

''(1) ELIGIBLE TAXPAYER.—The term 'eligible taxpayer' means any taxpayer which—

''(A) is not a foreign entity of concern (as defined in section 9901(8) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (15 U.S.C. 4651), and

''(B) has not made an applicable transaction (as defined in section 50(a)) during the taxable year.

''(2) ELIGIBLE COMPONENT.—The term 'eligible component' has the meaning given such term in section 45BB(c)(1).

''(3) PRODUCTION.—The term 'production' has the meaning given such term in section 45BB(c)(6).

''(d) TERMINATION OF CREDIT.—The credit allowed under this section shall not apply to property the construction of which begins after December 31, 2027.''.

(b) ELECTIVE PAYMENT.—Section 6417(a) of the Internal Revenue Code of 1986, as amended by section 2(b) of this Act, is amended by adding at the end the following new paragraph:

''(14) The generic drugs and biosimilars investment credit determined under section 48F.''.

(c) CONFORMING AMENDMENTS.—

(1) Section 46 is amended—

(A) in paragraph (6), by striking ''and'' at the end,

(B) in paragraph (7), by striking the period at the end and inserting '', and'', and

(C) by adding at the end the following:

"(8) the generic drugs and biosimilars investment credit.".

(2) Section 49(a)(1)(C) is amended—

(A) by striking "and" at the end of clause (vi),

(B) by striking the period at the end of clause (vii) and inserting a comma, and

(C) by adding at the end the following new clause:

"(viii) the basis of any qualified property which is part of a qualified facility under section 48F.".

(3) The table of sections for subpart E of part IV of subchapter A of chapter 1 is amended by inserting after the item relating to section 48E the following new item:

"48F. Generic drugs and biosimilars investment credit.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after December 31, 2025.

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